

Food and Drug Administration, HHS

§ 1002.41

basis for selecting such methods, devices, and procedures.

(3) For those products displaying aging effects which may increase electronic product radiation emission, records of the results of tests for durability and stability of the product, and the basis for selecting these tests.

(4) Copies of all written communications between the manufacturer and dealers, distributors, and purchasers concerning radiation safety including complaints, investigations, instructions, or explanations affecting the use, repair, adjustment, maintenance, or testing of the listed product.

(5) Data on production and sales volume levels if available.

(b) In addition to the records required by paragraph (a) of this section, manufacturers of products listed in paragraph (c) of § 1002.61 shall establish and maintain the following records with respect to such products:

(1) A record of the manufacturer's distribution of products in a form which will enable the tracing of specific products or production lots to distributors or to dealers in those instances in which the manufacturer distributes directly to dealers.

(2) Records received from dealers or distributors pursuant to § 1002.41.

[38 FR 28625, Oct. 15, 1973, as amended at 60 FR 48386, Sept. 19, 1995]

§ 1002.31 Preservation and inspection of records.

(a) Every manufacturer required to maintain records pursuant to this part, including records received pursuant to § 1002.41, shall preserve such records for a period of 5 years from the date of the record.

(b) Upon reasonable notice by an officer or employee duly designated by the Department, manufacturers shall permit such officer or employee to inspect appropriate books, records, papers, and documents as are relevant to determining whether the manufacturer has acted or is acting in compliance with Federal standards.

(c) Upon request of the Director, Center for Devices and Radiological Health, a manufacturer of products listed in table 1 of § 1002.1 shall submit to the Director, copies of the records

required to be maintained by paragraph (b) of § 1002.30.

[38 FR 28625, Oct. 15, 1973, as amended at 53 FR 11254, Apr. 6, 1988; 60 FR 48386, Sept. 19, 1995]

Subpart E—Dealer and Distributor Records

§ 1002.40 Records to be obtained by dealers and distributors.

(a) Dealers and distributors of electronic products for which there are performance standards and for which the retail price is \$50 or more shall obtain such information as is necessary to identify and locate first purchasers if the product is subject to this section by virtue of table 1 of § 1002.1.

(b) Such information shall include:

(1) The name and mailing address of the distributor, dealer, or purchaser to whom the product was transferred.

(2) Identification and brand name of the product.

(3) Model number and serial or other identification number of the product.

(4) Date of sale, award, or lease.

(c) The information obtained pursuant to this section shall be forwarded immediately to the appropriate manufacturer of the electronic product, or preserved as prescribed in § 1002.41.

[38 FR 28625, Oct. 15, 1973, as amended at 42 FR 18063, Apr. 5, 1977; 60 FR 48386, Sept. 19, 1995]

§ 1002.41 Disposition of records obtained by dealers and distributors.

(a) Information obtained by dealers and distributors pursuant to § 1002.40 shall immediately be forwarded to the appropriate manufacturer unless:

(1) The dealer or distributor elects to hold and preserve such information and to immediately furnish it to the manufacturer when advised by the manufacturer or the Director, Center for Devices and Radiological Health, that such information is required for purposes of section 359 of the Act; and

(2) The dealer or distributor, upon making the election under paragraph (a)(1) of this section, promptly notifies the manufacturer of such election; such notification shall be in writing and shall identify the dealer or distributor and the electronic product or